

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

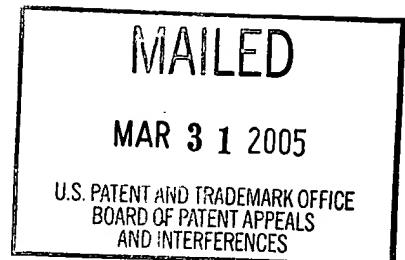
UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte PAOLO GIACOMONI

Appeal No. 2005-0593
Application No. 08/894,788

HEARD: March 15, 2005



Before WILLIAM F. SMITH, MILLS and GREEN, Administrative Patent Judges.

MILLS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. §134 from the examiner's final rejection of claims 1-2, 4-8, 10-13, 16-17, 22-23, 28-29 which are all of the claims pending in this application.

Claim 31 is illustrative of the claims on appeal and appears as follows:

31. A cosmetic or pharmaceutical composition, said composition comprising, in a cosmetically or pharmaceutically acceptable medium,
at least one cosmetic or pharmaceutical product capable of causing a cutaneous irritant effect, and

Appeal No. 2005-0593
Application No. 08/894,788

at least one topically applied nitric oxide synthase inhibitor, wherein said topically applied nitric oxide synthase inhibitor is present in an amount effective to reduce the cutaneous irritant effect of the at least one cosmetic or pharmaceutical product.

The prior art references relied upon by the examiner are:

Hahn et al. (Hahn)	5,716,625	Feb. 10, 1998
Wahl et al. (Wahl)	5,449,688	Sept. 12, 1995
Williamson et al. (Williamson)	5,358,969	Oct. 25, 1994

Reference cited by Merits Panel

Ptchelintsev et al. ('003)	5,847,003	Dec. 8, 1998 (filed June 4, 1996)
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Grounds of Rejection

Claims 31-38, 40-54 and 56-66 stand rejected under 35 U.S.C. 103(a) for obviousness over Hahn in view of Wahl or Hahn in view of Williamson or Hahn in view of Williamson and Wahl.

We reverse these rejections. The application is remanded to the examiner for consideration of the issues discussed herein.

DISCUSSION

35 U.S.C. § 103

Claims 31-38, 40-54 and 56-66 stand rejected under 35 U.S.C. 103(a) for obviousness over Hahn in view of Wahl or Hahn in view of Williamson or Hahn in view

Appeal No. 2005-0593
Application No. 08/894,788

of Williamson and Wahl.

In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. See In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). It is well-established that the conclusion that the claimed subject matter is prima facie obvious must be supported by evidence, as shown by some objective teaching in the prior art or by knowledge generally available to one of ordinary skill in the art that would have led that individual to combine the relevant teachings of the references to arrive at the claimed invention. See In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988).

It is the examiner's position that (Answer, page 3):

Hahn teaches a number of substances, which when applied topically can cause skin irritation. The substances include vehicles in which active ingredients are formulated (carriers), solvents, detergents, fragrances, propellants, salicylic acid derivatives, retinoids, etc., and cause irritation which ranges from mild irritation to severe dermatitis conditions.... Hahn teaches strontium cation as an anti-irritant (see entire document, particularly, cols. 1-4, 10 and 11) suggesting in general the use of an anti-irritant together with an irritant, in the same composition. However, Hahn fails to teach the claimed nitric oxide (NO) synthase inhibitor as anti-irritant.

The examiner relies on Williamson for its teaching of NO synthase inhibitors for the treatment of chronic and acute inflammatory conditions which include inflammatory dermatitis, drug reactions sunburn, insect bites, burns (thermal, chemical and electrical). Answer, page 4.

Appeal No. 2005-0593
Application No. 08/894,788

Williamson also teaches pharmaceutically acceptable diluents and carriers, which according to Hahn are capable of producing skin irritation. Answer, page 4. The examiner concludes (Answer, page 4) that:

[a] skilled artisan would be motivated to incorporate NO synthase inhibitors of Williamson et al as anti-irritants in the composition of Hahn et al containing irritant chemical [sic] and expect to counteract the irritant because Williamson et al teach NO synthase inhibitors are capable of inhibiting chemical induced chronic and acute dermatitis and Hahn teaches that chronic and acute dermatitis results due to the irritation caused by chemicals. Therefore it would have been obvious for a skilled artisan to substitute the strontium cation of Hahn et al with NO synthase inhibitors of Williamson et al, with an expectation to inhibit the irritation by [sic] caused by the substances of Hahn et al. Williamson does not teach topical application of nitrous oxide synthase inhibitor. However, applying nitrous oxide synthase inhibitors of Williamson et al as a topical formulation would have been obvious from the teachings of Hahn et al or alternatively, it is within the scope of the skilled artisan at the time of the instant invention to use topical formulations of nitric oxide synthase inhibitors a first line choice, with an expectation to produce a local effect.

Alternatively, the examiner argues that Wahl et al teach treatment of chronic inflammatory conditions such as psoriasis by administering the specific nitric oxide synthase inhibitors of the instant claims. Id. According to the examiner, "Wahl teaches several routes of administration, including topical application." Answer, pages 4-5. "Therefore, it would have been obvious for a skilled artisan at the time of the instant invention to use the nitric oxide synthase inhibitors of Wahl in the topical composition of Hahn with an expectation to inhibit the skin irritation caused by the various chemicals." Answer, page 5.

Appeal No. 2005-0593
Application No. 08/894,788

Appellant responds, arguing that Hahn "is not generic with respect to teaching anti-irritants, and nowhere does it suggest the substitution of strontium (II) metal cation with any other anti-irritant." Brief, page 7. Appellant argues that the "examiner has not pointed to any teaching or suggestion in Hahn that would have motivated the skilled artisan to replace the strontium (II) metal cation of Hahn with another anti-irritant -- and certainly not with a nitric oxide synthase inhibitor." Brief, page 7.

We agree with the appellants that the examiner has not provided sufficient evidence to establish a reason, suggestion or motivation to substitute a NO synthase inhibitor for strontium metal cation. It would appear clear from the record that strontium metal cation and NO synthase inhibitor function in different ways when applied to the skin. Thus, it does not appear that strontium metal cation and NO synthase inhibitor would be considered by those of ordinary skill in the art to be equivalent compounds which are readily substitutable for one another.

Appellant argues that Williamson and Wahl are directed to systemic administration of specific amino acids for treating and preventing acute or chronic inflammatory diseases caused by intracellular nitric oxide production. Brief, pages 10 and 11. Appellants argue that Hahn is not directed to systemically decreasing or preventing nitric oxide formation in the cells at all, let alone by the use of nitric oxide synthase inhibitors. Brief, page 10. Thus, appellants conclude that when the references are reviewed as a whole, the references do not provide a motivation that suggests their combination, as Williamson and Wahl are directed to treating one

Appeal No. 2005-0593
Application No. 08/894,788

problem with one solution, while Hahn is directed to treating a distinctly different problem with a distinctly different solution. Brief, page 10.

We agree with appellants, that while Wahl does suggest that NO synthase inhibitors may be administered topically by transdermal patches, we note that Wahl does not describe topical application of NO synthase inhibitor, such as by a cream or gel to the skin. In our view, the method of topical application via a transdermal patch described in Wahl is more consistent with systemic delivery of the NO synthase inhibitor and not topical application of NO synthase inhibitor in general. While Wahl in a sense describes topical administration to skin directly under the patch, we find no suggestion that Wahl is topically administering the patch as a treatment for an irritated part of the skin.

Appellants argue that the examiner has failed to establish a prima facie case of obviousness. Brief, page 8. In particular, appellants argue that the combination proposed by the examiner lacks the requisite motivation to combine the cited references. Brief, page 11.

We agree with appellants that the examiner has failed to establish a prima facie case of obviousness on the facts before us for the reasons discussed herein. In our view, the examiner has not established by a preponderance of the evidence why one of ordinary skill in the art, with knowledge of Hahn, Wahl and Williamson, would have been motivated to select the particular NO synthase inhibitor for use in a topical cosmetic or pharmaceutical composition as we do not find NO synthase inhibitor to be

Appeal No. 2005-0593
Application No. 08/894,788

an equivalent of strontium metal cation.

What is also missing from the examiner's analysis is evidence of topical application of NO synthase inhibitor. While Wahl and Williamson reference topical application by a transdermal patch, such topical application is administered for systemic delivery of the NO synthase inhibitor, not as a "topical" treatment of the skin.

In view of the above, the rejection of claims 31-38, 40-54 and 56-66 stand rejected under 35 U.S.C. 103(a) for obviousness over Hahn in view of Wahl or Hahn in view of Williamson or Hahn in view of Williamson and Wahl is reversed.

Other Issue

The present application is remanded to the examiner to consider the applicability of U.S. Patent No. 5,847,003 ('003) to the pending claims. The '003 patent was filed June 4, 1996, which is prior to the August 27, 1997 filing date of the present application. We also note the present application is a 371 of PCT/FR96/00296 filed February 2, 1996 which claims priority to French application 95/02267 filed February 27, 1995. It does not appear from the record that an English Translation of the French priority document has been filed. Thus, it cannot be determined if the claims on appeal are entitled to the benefit under 35 U.S.C. § 119.

In particular, '003, column 9, lines 40-46, describes the "coformulation of oxa acids with nitric oxide synthase inhibitors as a way of reducing skin redness, vasodilation and inflammatory reactions, especially in response to electromagnetic and

Appeal No. 2005-0593
Application No. 08/894,788

ionizing radiation or to the action of chemically or biochemically aggressive [sic] compounds." It would reasonably appear that the chemically or biochemically aggressive compounds of the '003 patent would be understood by those of ordinary skill in the art to be irritant compounds, as required by claim 31 on appeal. "The nitric oxide synthase inhibitors can be added at concentrations from about 0.05% to 10%, most preferably from 1% to 3%" '003, column, line 47. Compare present specification, page 12.

The examiner should carefully review the disclosure of the '003 patent, determine its relevance to the pending claims, and enter a rejection of the claims, if appropriate. It is also recommended that the examiner update the original search.

CONCLUSION

The rejection of claims 31-38, 40-54 and 56-66 under 35 U.S.C. 103(a) for obviousness over Hahn in view of Wahl or Hahn in view of Williamson or Hahn in view of Williamson and Wahl is reversed. The application is remanded to the examiner to consider the applicability of U.S. Patent No. 5,847,003 ('003) to the pending claims.

Appeal No. 2005-0593
Application No. 08/894,788

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

REVERSED AND REMANDED

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Demetra J. Mills)
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Appeal No. 2005-0593
Application No. 08/894,788

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